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CLINICAL INVESTIGATION SERVICE

ANNUAL PROGRESS REPORT FISCAL YEAR 1977

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18. SUPPLEMENTARY NOTES This report summarizes research conducted under protocol by staff members. Areas investigated include:		
19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Brucella sp., Carcinoma, Cardiology, Chemical Pain, Choline Phosphotransferase, Gallium, Dentistry, Electron Microscopy, Endocrinology, Gas Chromatography, Gastroenterology, Gynecology, Infectious Disease, (over)		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) This report serves to detail the progress, status, and funding of approved projects conducted under protocol by staff members, interns, and residents at William Beaumont Army Medical Center. The varying projects are reported and classified according to the service or department to which the investigator belongs. Research conducted at WBAMC is categorized as basic experimental medicine or trials and testing of clinical medicine procedures using the indigenous population for which this medical facility provides support.		

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CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

REPORT NO. 12

30 September 1977

CLINICAL INVESTIGATIONS (U)

FOREWORD

The Clinical Investigations Service, formerly the Medical Research and Development Service, is entering its 13th year of operation. Efforts to utilize the best research principles and techniques available for the production of the most reliable results continue.

The investigators for each work unit are identified in their respective reporting sections. The contributions of the many nurses, technicians, corpsmen, and administrative personnel who are vital to the successful implementation of clinical research projects are acknowledged.

This year marked the end of an era for the WBAMC Clinical Investigations Service. The unit's first and only Chief, Martin L. Nusynowitz, M.D., COL, MC, retired in September 1977 after 20 years of meritorious military service. His accomplishments were many and his successor is grateful for the foundations laid.



L. L. PENNEY, M.D.
LTC, MC
Chief, Clinical Investigations Svc

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UNIT SUMMARY

OBJECTIVES

The Clinical Investigations Service of William Beaumont Army Medical Center was established 2 February 1965 as the Medical Research and Development Service. The mission is to promote and coordinate clinical research. The Service supports in-house research projects by AMEDD staff members, residents, and interns, assisting in the formulation, preparation, and promulgation of research protocols and final research publications. The service furnishes experimental design and statistical and technical expertise, develops and carries out special laboratory procedures, and provides general support in terms of equipment, supplies, and animal resources when necessary. The creative and inspirational environment and technical knowledge available serve to stimulate the undertaking of basic and clinical medical and paramedical research at William Beaumont Army Medical Center by staff members, and interns and residents in training, as well as provide a basic instructional facility to elucidate the principles and conduct of research.

TECHNICAL APPROACH

The Clinical Investigations Service provides support for staff research projects under the guidelines of the Declaration of Helsinki, Clinical Investigation Program (AR 40-38), and the Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances (AR 40-7). Research is conducted under protocols approved by the Research Committee (WBAMC HR 70-4), the Human Use Committee (WBAMC HR 40-38) and the Radioisotope Committee (WBAMC HR 40-37) where applicable. In those research protocols utilizing laboratory animals, the investigators follow guidelines set forth in "Guide for Laboratory Animal Facilities and Care," published by the Committee on the Guide for Laboratory Animal Facilities and Care of the Institute of Laboratory Animal Resources, National Academy of Sciences-National Research Council, and to the criteria established by The American Association for Accreditation of Laboratory Animal Care.

MANPOWER

<u>Title</u>	<u>SSI/MOS</u>	<u>Auth</u>	<u>Assigned</u>	<u>Name</u>
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Vet Lab Anim Off	64C	0-3	0-3	Gee, T.E., VC
Med Lab Sp	92B30	E-5	E-6	Rounsavill, M.A.
Vet Anim Sp	91T20	E-4	E-5	Joyner, J.M.
Vet Anim Sp	91T20	E-3	E-2	Lee, Daniel F
Vet Anim Sp	91T10	E-3	E-2	Graf, James P

MANPOWER

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Anm Caretaker	07706	WG-3	WG-1	Burton, A.D.
Chemist	01311	GS-11	GS-11	Kutsky, R.J.
Microbiologist	00403	GS-11		
Chemist	01320	GS-9	GS-9	Sandison, S.W.
Med Lab Technl	00644	GS-11	GS-11	Banez, R.J.
Med Lab Tech	00645	GS-7	GS-7	Manna, B.S.
Med Lab Tech	00645	GS-7	GS-6	Teasley, C.E.
Editorial Asst	01087	GS-7	GS-7	Casteel, P.J.

FUNDING (Excluding Military Salaries)

Note FY7T and FY77 are combined

EXPENDITURES	FY75	FY76	FY7T & FY77
Personnel (Civilian, O&MA)	90922	89914	148153
Minor Equipment and			
Consumable Supplies(O&MA)	19338	20471	56831
Capital Equipment(OPA)	59921	49739	48324
TDY			3485
Other Purchases & Svcs			3705
Printing & reproduction			622
TOTAL	170181	160123	261120

PROGRESS

The Clinical Investigations Service entered FY7T and FY77 with 54 protocols ongoing from previous years. Twenty-five new protocols were approved for a total of 79 sponsored studies. Eighteen protocols were completed and 15 were terminated. Forty-six protocols are ongoing and will be continued in FY78.

The Service needs several items of major equipment replaced and needs several new items to fully support the protocols and accomplish our mission.

The major problem is unchanged. There is a shortage of manpower and expertise. Since the last report the Service has been without the following military members: (1) Biochemist/Asst Chief for four months; (2) Vet Lab Animal Off for four months; (3) Vet Anim Sp for two months; (4) Vet Anim Sp for two months; (5) Biochemical Sci Asst for 15 months. In addition the GS-11 Chemist, GS-9 Chemist and GS-7 Med Lab Tech all retired or resigned. The GS-11 Microbiologist resigned in Aug 77 and has not been replaced. Of 135 authorized civilian man-months in FY7T and FY77, only 115 were filled. This, of course, is compounded by the fact that the new people must be oriented and trained.

Despite this loss of manpower the comptroller reported an increase in civilian personnel costs from \$89,914 in FY76 to \$120,804 in FY77 excluding FY7T. Hopefully this is correct and reflects the drastic shortages of preceding fiscal years only somewhat corrected in FY77.

During this FY the Clinical Investigations Service sponsored sixteen publications and eight presentations.

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Immunoassay for Antidiuretic Hormone

WORK UNIT NO: 66/115

PRINCIPAL INVESTIGATOR: COL M.L. Nusynowitz, MD

ASSOCIATE INVESTIGATORS: CPT N. L. Sass, PhD

OBJECTIVES

To develop a radioimmunoassay for antidiuretic hormone.

TECHNICAL APPROACH

Antidiuretic hormone will be coupled onto a larger protein molecule and efforts will be made to develop antibody to this complex in rabbits. The antibody will be reacted with known amounts of radioactive antidiuretic hormone and unknown amounts of "cold" hormone. Measurement of amount of labelled hormone reacting gives a measure of the amount of unlabelled hormone present.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FYY76	\$1684	\$350	-	\$2034
FY77	-	-	-	-

PROGRESS

Methods previously attempted have proved largely unsuccessful. New techniques being developed were also unsuccessful. The test is now available elsewhere as a standard assay.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Gas Chromatography of Thyroid Hormones

WORK UNIT NO: 72/01

PRINCIPAL INVESTIGATOR: CPT N.L. Sass, PhD

ASSOCIATE INVESTIGATORS: B. Manna, DAC

OBJECTIVES

To develop GLC methods for MIT, DIT, T3, T4

TECHNICAL APPROACH

Silylation reaction derivatives of amino acids will be prepared to facilitate detection by gas chromatographic techniques of separate iodoamino acids from serum.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$2357	\$ 1375	\$1900	\$5632
FY77	7408	1656	-	9064

PROGRESS

Development of the technique for MIT, DIT determination by gas chromatography was successful. The paper was submitted for publication. The clinical studies (Phase II) were inconclusive and were terminated.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Further Characterization of the DNA of Cryptococcus neoformans

WORK UNIT NO: 74/11

PRINCIPAL INVESTIGATOR: Keith Erke, PhD (DAC)

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Since the DNA isolated from C. neoformans precipitates in nonspoolable floccules rather than the typically spoolable DNA preparations characteristic of most other organisms, it is the object of this study to assess the purity and molecular weight of DNA prepared from this yeast. It is also of interest to determine the relative amounts of nuclear and mitochondrial DNA present in these preparations.

TECHNICAL APPROACH

The purity of DNA isolated from C. neoformans will be determined by establishing ratios of U.V. absorption at 230, 260, and 289 nm and by assaying for protein, RNA and heteropolysaccharide. Polyacrylamide gel electrophoresis and hydroxylapatite columns will be used to further purify and/or assess the purity of DNA preparations. The molecular weights of the DNA fragments will be estimated by determining sedimentation rates on sucrose gradients to determine the relative amounts of mitochondrial and nuclear DNA present.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$2357	\$1100	-	\$3457
FY77	\$6519	\$1250	-	\$7769

PROGRESS

The principal investigator has departed. Any publications will be included in the FY78 report.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Elucidation of Events Occurring During Hyphal Formation of
Some Cryptococcus neoformans strains.

WORK UNIT NO: 74/12

PRINCIPAL INVESTIGATOR: Keith Erke, PhD (DAC)

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this investigation was to study the formation of basidia and basidiospores in three hypha-forming strains of C. neoformans. Attempts are also being made at carrying out genetic analysis in these strains of this pathogenic yeast.

TECHNICAL APPROACH

The morphological development of basidia and basidiospores were recorded with a photomicroscope. The nuclear patterns in basidiospores and hyphae were determined by Giemsa staining. Basidiospores were isolated by micromanipulation in order to observe their germination and to determine their ability to complete the sexual life cycle. Genetic analysis is conducted by mating auxotrophic mutants and looking for recombinant types among the progeny.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$2357	\$1350	-	\$3707
FY77	6519	1250	-	\$7769

PROGRESS

The principal investigator has departed. Any publications will be included in the FY78 report.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Assessment of Mediation Factors Involved in Chemical Pain Responses

WORK UNIT NO: 75/27

PRINCIPAL INVESTIGATOR: CPT N. Sass, PhD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the endogenous chemical mediators for the production of a chemical pain response and delineate parameters of chemoreceptor foci involved in the formation of a chemical pain response.

TECHNICAL APPROACH

Various chemical irritants will be topically applied to test animal skin to elicit the formation of blisters. The fluid contained in these blisters will be withdrawn and analyzed using various instrumental and chromatographic techniques to determine: (1) Basic patterns of fluid contents withdrawn from blisters formed as a result of using varying classes of chemical irritant compounds. (2) Determine differences in these patterns compared to those produced by capsaicin (N-(4-hydroxy-3-methoxybenzyl)non-trans-6-enamide) an irritant extracted from species of chili peppers which is known to induce resistance or immunity from further applications of chemical irritants. (3) Differential structures and/or affinities for chemoreceptor binding sites based on the structures or compositions of mediators found in the blister fluids.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$1683	400	-	\$2084
FY77	\$4741	1819	-	6560

PROGRESS

A much improved procedure for the purification of capsaicin has been developed and a paper detailing the technique has been published. Animal studies were not initiated due to departure of the investigator.

STATUS: Completed.

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Isolation and Purification of Choline Phosphotransferase

WORK UNIT NO: 75/30

PRINCIPAL INVESTIGATOR: LTC L.L. Penney, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To develop a method for the isolation of choline phosphotransferase from lung tissue and correlate respiratory distress with the presence and specific activity of this enzyme.

TECHNICAL APPROACH

Purification of microsomal and lysosomal fractions of lung tissue will be subjected to standardized enzyme purification techniques. Cofactor effects will be studied in order to access possible prophylaxis development in cases of respiratory distress.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$1684	\$1650	\$2500	\$5830
FY77	4741	1818	857	7416

PROGRESS

Isolation attempts of lamellar body fractions and lysosomal fractions isolated by amniotic fluid ultracentrifugation was subjected to column chromatography in an attempt to further isolate and purify this enzyme. This approach is still being investigated.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Mode of Action of the 4-quinazolones(I): CNS Active Drugs

WORK UNIT NO: 76/16

PRINCIPAL INVESTIGATOR: Joel Martin (DAC)

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study the pharmacology, pharmacokinetics, and effect on various enzymes of the 4-Quinazolones in various organs of the body in an attempt to determine the exact mode of action of this family of CNS depressants.

TECHNICAL APPROACH

Laboratory animals are injected with methaqualone (2-methyl-3-o-tolyl-4 (3H)-Quinazolone). At various time intervals (1,3,6, and 24 hours) the animals are sacrificed and the various organs collected. The amount of Methaqualone in the various organs are determined by either Gas Chromatography, Thin Layer Chromatography, UV Spectrophotometry, or Colorimetric techniques. Enzyme levels are determined by biochemical assays.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$2357	\$ 150	-	\$2500
FY77	6519	400	-	6919

PROGRESS

Eighteen laboratory animals were injected with Methaqualone. They were sacrificed at intervals stated above. Various organs were used to establish an analytical procedure for the determination of Methaqualone in tissue samples. A quantitative procedure was developed for gas chromatography as well as for ultraviolet spectroscopy. Paper is being prepared for submission to Clinical Chemistry Journal.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Study of Immune Response to Experimental Infection with
Brucella melitensis

WORK UNIT NO: 76/21

PRINCIPAL INVESTIGATOR: SP5 Steve Raymond

ASSOCIATE INVESTIGATORS: MAJ E Young, MD; CPT N Sass PhD; K. Erke PhD

OBJECTIVES

The object of this study is to evaluate the possible correlation between development of delayed-type hypersensitivity (DTH) and development of cell-mediated immunity (CMI) to bacterial endotoxins as shown in migration inhibition factor (MIF) and lymphocyte transformation studies.

TECHNICAL APPROACH

This will be accomplished by experimental infection of guinea pigs with a specific endotoxin antigen derived from the cell walls of Brucella melitensis by fractionation methods. Upon subsequent infection, the experimental animals will be tested for production of MIF by standard methods as well as lymphocyte transformation studies using a RIA technique.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$2357	\$ 100	-	\$2457
FY77	6519	250	-	6769

PROGRESS

As of this date, the study of immune response to experimental infection with Brucella melitensis is completed except for the final technical writing phase. The evaluation of a possible correlation between development of cell-mediated immunity to bacterial endotoxin was completed using migration inhibition factor assay and lymphocyte transformation studies. There is a correlation between development of delayed-type hypersensitivity and bacterial lipopolysaccharide found in the endotoxin produced by B. melitensis. Another correlation is hypothesized to explain the relationship between bacterial cell wall remnants that caused positive lymphocyte transformation as well as positive skin test results indicating development of delayed-type hypersensitivity and cell-mediated immunity to the same by-product.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: In Vivo Effect of Mitogenic Proteins on Granulopoiesis Following
Bone Marrow Suppression

WORK UNIT NO: 77/17

PRINCIPAL INVESTIGATOR: Roman Kutsky, DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To ascertain physiological functions of nucleoprotein factor (NPF) as relates to its mitogenic activity and the acceleration of granulopoietic recovery in drug-induced agranulocytic mice.

TECHNICAL APPROACH

Mice will be made agranulocytic using either BCNU or vinblastine sulfate. Nucleoprotein factor will be administered on a daily regimen for six days. CBC's and blood smears will be taken serially for ten days following the end of treatment to ascertain the effects of nucleoprotein factor on the recovery of bone marrow cells.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$8889	\$1300	\$857	\$11,046

PROGRESS

An improved streamlined extraction procedure has doubled previous yields, and the nucleoprotein factor has been stabilized. Sufficient quantities for animal testing are currently being generated, and cooperative arrangements with other laboratories for biological testing are being set up.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Effect of Catecholamines and Antagonists on Insulin Dependent
Glucose Uptake by the Bladder of Bufo Marinus

WORK UNIT NO: 77/27

PRINCIPAL INVESTIGATOR: COL M L Nusynowitz, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the mechanism of action of insulin on glucose transport
across the toad bladder.

TECHNICAL APPROACH

The toad bladder epithelium appears to be an analog of the distal tubule
collecting duct complex of the mammalian kidney. The effects of alpha
and beta adrenergic blocking drugs on glucose transport in this system
will be studied.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$ 889	\$150	-	\$1039

PROGRESS

Analytical techniques have been perfected and animal studies have begun.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Clinical Application of Decamethazone in Traumatic Oral Surgery

WORK UNIT NO: 76/25

PRINCIPAL INVESTIGATOR: MAJ LeMoine, DC

ASSOCIATE INVESTIGATORS: MAJ Kempf, DC, and LTC Adams, DC

OBJECTIVES

Evaluation of the efficacy of steroids in routine surgical removal of impacted third molars.

TECHNICAL APPROACH

Patients with bilateral lower third molars of equal symmetrical difficulty in removal will be admitted to this study. A double blind administration of either decamethasone or placebo will be given prior to the removal of the first molar. Subsequent removal of the second molar will be accompanied by administration of the second compound, depending upon which was first administered. Radiographic and photographic assessments will be correlated to the subjective pain experienced by the patient.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$1684	-	-	\$1684
FY77	4741	\$3000	\$6348	14,089

PROGRESS

Due to transfer of both the principal and associate investigators this project has been terminated by the Oral Surgery Service.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: An Analysis of Ameloblastic Fibro-odontoma

WORK UNIT NO: 77/20

PRINCIPAL INVESTIGATOR: COL George J Tsagaris, DC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The goals of this research study are to report upon and analyze cases of ameloblastic fibro-odontoma and to correlate these findings with those of earlier investigators in an attempt to clarify the misunderstanding concerning this particular odontogenic tumor.

TECHNICAL APPROACH

A retrospective analysis of 77 cases referred to the Oral Pathology Department of the Armed Forces Institute of Pathology with reference to the clinical features, radiographic appearance and histologic characteristics of this entity.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$889	-	-	\$889

PROGRESS

Followup on twenty patients is in process.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Regional Myocardial Blood Flow

WORK UNIT NO: 69/338

PRINCIPAL INVESTIGATOR: COL M.L. Nusynowitz, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To devise a method for determination of regional changes in the blood supply to the myocardium.

TECHNICAL APPROACH

Selective catheterization of coronary arteries will be performed on anesthetized, well ventilated, mongrel dogs using preformed coronary catheters. After confirmation of the position of the catheter, ¹³³Xenon will be rapidly injected into the coronary artery. The animal's heart will be centered beneath a ten inch scintillation camera collimator. The image produced by this camera will be photographed at appropriate intervals to produce both visualization of the coronary arterial tree and washout of the xenon.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$673	-	-	\$673
FY77	-	-	-	-

PROGRESS

Technical difficulties in the use of Xe-133 for myocardial blood flow determinations were insurmountable. The investigator has now departed.

STATUS: Terminated.

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Antibody Detection in Hepatitis Type B

WORK UNIT NO: 73/24

PRINCIPAL INVESTIGATOR: MAJ J Prather, MC

ASSOCIATE INVESTIGATORS: MAJ Alan Hughes, MC

OBJECTIVES

To provide a simple radioimmunoassay kit for the assessment of antibody titers in patients with exposure to Hepatitis Type B.

TECHNICAL APPROACH

Available kit for determination of the presence of Hepatitis Type B antigen was converted to a kit for assay of the antibody. Studies were undertaken with this method; however, a commercial antibody kit was marketed and studies were then performed with this kit.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$ 337	-	-	\$337
FY77	888	-	0	\$888

PROGRESS

Initial data evaluation proved discouraging and the project was discontinued.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Gallium-67 Citrate in the Diagnosis of Soft Tissue Tumors

WORK UNIT NO: 74/18

PRINCIPAL INVESTIGATOR: COL M. L. Nusynowitz, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate ⁶⁷Gallium Citrate for use in the diagnosis of soft tissue tumors and inflammatory disease.

TECHNICAL APPROACH

Patients with documented neoplasm or those highly suspect of having soft tissue neoplasm or occult abscesses are given intravenous injections of Gallium citrate and subsequently scanned.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$ 337	-	-	\$ 337
FY77	-	-	-	-

PROGRESS

Ga-67 citrate has been granted a New Drug Application by FDA and is no longer investigational.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Mechanisms of Brucella Endotoxin Effects in Experimental Animals

WORK UNIT NO: 74/34

PRINCIPAL INVESTIGATOR: MAJ E.J. Young, MD

ASSOCIATE INVESTIGATORS: Keith Erke, PhD (DAC)

OBJECTIVES

To determine, using an experimental animal model, the role of Brucella endotoxin in the pathogenesis of brucellosis.

TECHNICAL APPROACH

The isolation of endotoxin from B. melitensis will be conducted. Studies on lethality of this substance in mice, and studies of its pyrogenicity in rabbits, using an established animal model, will be done as well as studies on the role of sensitization to this antigen in the above reactions and the role, if any, of humoral and cellular antibodies.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY 76	\$1683	\$100	-	\$1780
FY77	\$4740	\$3000	-	\$7740

PROGRESS

The principle investigators have departed and the data are being analyzed. If any publications or presentations eventuate they will be included in the FY78 report.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Normal Values of Serum Triiodothyronine (T3) as Determined by
Radioimmunoassay in Various Clinical Euthyroid States

WORK UNIT NO: 75/07

PRINCIPAL INVESTIGATOR: COL M. Nusynowitz, MD; Jerome Waliszewski DAC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Determine normal values of T3 for: (a) Pregnancy during all three trimesters. (b) Females taking oral contraceptives. (c) Euthyroid Hashimoto's Disease. (d) Other thyroiditides.

TECHNICAL APPROACH

Serum samples will be obtained from patients during 1st, 2nd, and 3d trimester of pregnancy; females on oral contraceptives for at least 3 months; euthyroid patients with Hashimoto's thyroiditis before treatment with thyroid hormone and after treatment with Synthroid; patients with thyroiditis (subacute). Clinical histories will be obtained and the clinical thyroid state will be determined. The serum samples obtained will be evaluated by radioimmunoassay. Determination of the inclusion into the proposed categories will be from clinical diagnosis, clinically determined thyroid state and appropriate laboratory studies.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$337
FY77	888	-	-	888

PROGRESS

Papers have been published in Clinical Nuclear Medicine reporting studies of T3 values in pregnancy and in patients with chronic renal failure on dialysis. Studies in other euthyroid states are ongoing.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Incidence of Splenomegaly in Patients with Primary Carcinoma of the Colon

WORK UNIT NO: 75/10

PRINCIPAL INVESTIGATOR: MAJ B. Mazat, MD: MAJ J.L. Prather, MD

ASSOCIATE INVESTIGATORS: COL M.L. Nusynowitz, MD

OBJECTIVES

To determine the incidence of isolated splenomegaly as noted on radio-colloid scanning of the liver and spleen in patients with carcinoma of the colon.

TECHNICAL APPROACH

A retrospective review of the scans and medical histories of all patients with carcinoma of the colon registered with the Tumor Board, WBAMC, from 1968-1974 is intended. Splenic size will be determined from the radio-colloid scan by the method of Larson. Coincident liver abnormalities will be noted; patients with evidence of significant liver pathology will be excluded. Data obtained will be analyzed to determine the incidence of splenomegaly in patients with carcinoma of the colon.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$337
FY77	-	-	-	-

PROGRESS

Data analysis indicated that there was no significant incidence of splenomegaly in these patients.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Diagnostic Adrenal Scanning with ^{131}I -Iodocholesterol

WORK UNIT NO: 75/23

PRINCIPAL INVESTIGATOR: MAJ J Prather, MC

ASSOCIATE INVESTIGATORS: MAJ F Gluck MC; COL M Nusynowitz MC;
MAJ A Hughes, MC

OBJECTIVES

To determine the usefulness of ^{131}I -Iodocholesterol in scanning of the adrenal glands.

TECHNICAL APPROACH

Patients with clinical evidence of adrenal disease will be thoroughly evaluated by an endocrinologist. Following intravenous administration of ^{131}I -Iodocholesterol, adrenal scanning will be performed after 7-10 days. The material will be obtained from the Nuclear Pharmacy, University of Michigan. The WBAMC Radiopharmacist will perform sterility and pyrogenicity tests on the radiochemical to insure that radiopharmaceutical standards are met prior to injection. DD Form 1573 will be filed with the supplier prior to the use of the material in patients.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$337
FY77	-	-	-	-

PROGRESS

I-131 iodocholesterol yielded useful studies, but the drug is no longer available. A superior agent, I-131 NP59, is currently being used (see Work Unit No. 76/33).

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: ^{99m}Tc -Sn-DTPA Chelate in the Detection of Vesicoureteral Reflux

WORK UNIT NO: 75/24

PRINCIPAL INVESTIGATOR: MAJ J Prather, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine the usefulness of ^{99m}Tc -Sn-DTPA chelate as a renal imaging agent, and particularly in the demonstration of vesicoureteral reflux.

TECHNICAL APPROACH

Patients with known or suspected vesicoureteral reflux will be studied with ^{99m}Tc -Sn-DTPA. The results obtained will be compared with clinical findings, laboratory tests, androentgenographic studies. Commercially available radiopharmaceutical Sn DTPA preparation kits will be employed. The kits will be supplied by Diagnostic Isotopes, Inc., 123 Pleasant Ave, Upper Saddle River, NJ. These kits are supplied in sterilized and pyrogen-free form. Other suppliers will be sought only if their product appears to be far superior and only from those manufacturers who have filed an IND with the Food & Drug Administration. Several mCi of radiopertechnetate are followed for radiopharmaceutical preparation.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$337
FY77	-	-	-	-

PROGRESS

We have recently received permission to study children below the age of 13 with this technique and this will allow us to proceed more vigorously with the study.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

Mechanisms Involved in the Formation of 99mTc Labeled
Topic: Diphosphonate & Pyrophosphonate as Bone Scanning Agents

WORK UNIT NO: 76/03

PRINCIPAL INVESTIGATOR: John Straw, DAC

ASSOCIATE INVESTIGATORS: N.L. Sass, CPT, PhD

OBJECTIVES

To determine the chemical reaction mechanism and identify products of the reaction used to produce diphosphonate or pyrophosphate bone scanning compounds.

TECHNICAL APPROACH

Commercial kits and in-house prepared kits will be used with 99mTc from various sources in the preparation of diphosphonate and pyrophosphate. A rigorous organic/inorganic qualitative and quantitative analysis using chromatographic (TLC, liquid), electrophoretic, and instrumental (IR, UV, MS) techniques will be conducted. Sufficient samples will be analyzed to establish statistical significance of any new quality control measures developed.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$2357	\$ 65	-	\$2422
FY77	-	-	-	-

PROGRESS

Technetium chemistry is still largely an undefined body of knowledge in the scientific community. Investigations necessary to define the mechanisms of bone agent foundation and action were found to be beyond the capabilities of this institution after the departure of the principle investigator who was the radiopharmacist.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Assessment of Various Chromatographic Procedures Determination of
Optimal Quality Control Methods for 99mTc Pharmaceuticals

WORK UNIT NO: 76/05

PRINCIPAL INVESTIGATOR: John Straw, DAC

ASSOCIATE INVESTIGATORS: CPT A R Benedetto

OBJECTIVES

To evaluate various chromatographic systems in order to determine the most optimal and rapid system for quality control of Tc-laboratory radiopharmaceuticals so that procedures can be completed before product use.

TECHNICAL APPROACH

Different chromatographic systems will be evaluated by varying system parameters including solvent systems and various support media themselves. A determination of the most rapid and easily performed procedure that still give adequate but definitive results will be made.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$2357	\$3500	-	\$5857
FY77	4741	1500	-	6241

PROGRESS

Sephadex gel filtration chromatography was found to provide reliable analysis of Tc-99m Human Serum Albumin, but it is too slow for daily quality control. A paper has been submitted reporting this work. A presentation was made to the Southwestern Chapter of the Society of Nuclear Medicine regarding the use of a computerized gamma camera analysis of ITLC strips.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Myocardial Perfusion Scanning with Radioactive Particles

WORK UNIT NO: 76/14

PRINCIPAL INVESTIGATOR: COL M L Nusynowitz, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To demonstrate myocardial perfusion at the capillary level as an aid in differentiating those patients who are likely to benefit from coronary artery surgery. The injection of radioactive particles in each coronary artery will demonstrate runoff perfusion. This will provide supplemental information to determine candidates for coronary artery surgical procedures.

TECHNICAL APPROACH

Tc^{99m} microspheres and I-131 macroaggregated albumin will be injected into the left and right coronary artery respectively at the time of cardiac catheterization. Imaging will be performed with a gamma camera and the images will be studied for areas of decreased perfusion.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$ 337	-	-	\$337
FY77	\$ 888	\$1000	-	\$1888

PROGRESS

Excessive workloads and shortage of physicians in Cardiology Service have prevented initiation of studies. The expected availability of cardiac catheterization facilities and the arrival of two new cardiologists may permit studies to begin during the next fiscal year.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Thallium-201 Chloride for Diagnosis of Myocardial Ischemia and/or Myocardial Infarction

WORK UNIT NO: 76/15

PRINCIPAL INVESTIGATOR: COL M L Nusynowitz, MD

ASSOCIATE INVESTIGATORS: Nuclear Medicine & Cardiology Staff

OBJECTIVES

To evaluate the clinical efficacy of Thallium-201 Chloride in delineating areas of infarcted myocardium with regard to presence, extent, and healing and to delineate areas of myocardial ischemia under resting and/or exercise conditions.

TECHNICAL APPROACH

Patients with suspected myocardial infarction or ischemia will be injected with Thallium 201-Chloride. This material, an analog of potassium, is concentrated in well perfused normal myocardium and is not taken up by ischemic myocardia. Images will be obtained to evaluate presence, size, and changes in hypoperfused myocardium under resting or exercise conditions as an aid to the clinical management of these patients.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$ 337	-	-	\$337
FY77	\$ 888	\$2000	-	\$2888

PROGRESS

More than 200 patients have been studied to date. Thallium 201-Chloride appears to be an excellent agent for diagnosing cardiac ischemia, especially when stress/resting imaging is used.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

Liver Biopsy Sampling Error in Chronic Hepatitis Role of
TITLE: Laparoscopically Guided Multiple Liver Biopsies

WORK UNIT NO:76/18

PRINCIPAL INVESTIGATOR:MAJ Fred Goldner

ASSOCIATE INVESTIGATORS:MAJ J Greene, COL J L Pitcher

OBJECTIVES

To determine whether the severity of the histologic lesion of chronic active hepatitis varies in distribution throughout the liver. Currently a single percutaneous biopsy is used to diagnose and help guide therapy. If there is significant variation in distribution of the pathology, this latter approach may be inadequate.

TECHNICAL APPROACH

Laparoscopy will be used to view the liver of 15 patients with chronic active hepatitis. Four liver biopsies will be obtained from various areas of the liver. Biopsies will be coded and blindly evaluated for certain histologic parameters. Differences among biopsies will be compared.

FUNDING:	<u>Civ Sal</u>	<u>Equip,Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$ 337
FY77	888	-	-	888

PROGRESS

No statistically significant difference in diagnostic efficacy was found between multiple biopsies and a single biopsy in chronic liver disease. The results of the study were presented at the annual meeting of the American Society for Gastrologic Endoscopy at Toronto in May 1977.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Effect of a Broad Spectrum Antibiotic on the Course of
Viral URI

WORK UNIT NO: 76/23

PRINCIPAL INVESTIGATOR: MAJ E. Young, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine in a controlled double-blind study the effect of an anti-biotic on the clinical course of acute viral upper respiratory tract infections with particular attention to any beneficial or deleterious effects of the treatment with respect to secondary bacterial complications.

TECHNICAL APPROACH

Patients admitted to the Acute Respiratory Distress (ARD) Ward without obvious bacterial infections were to be divided into two random groups. One group to receive tetracycline HCL, the other a placebo. The physician taking care of the patients, and the patients themselves, would not know whether they were receiving drug or placebo. The code would be held by the Pharmacy Service. The incidence of complications, in particular, secondary bacterial infections; the total length of fever; the general well-being; length of hospital stay; incidence of adverse drug reaction; and the total cost of treatment would be compared between the two groups.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$337
FY77	-	-	-	-

PROGRESS

Dr. Young's successor is currently reviewing this protocol and will begin the study during early FY78.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: ^{99m}Tc Pyrophosphate Bone Scanning Agents in the Diagnosis and
Assessment of Myocardial Infarction

WORK UNIT NO: 76/27

PRINCIPAL INVESTIGATOR: COL M L Nusynowitz, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this study is to determine the suitability and efficacy of ^{99m}Tc pyrophosphate as myocardial scanning agent in suspected or proven myocardial infarction. Conditions to be studied: (1) Suspected myocardial infarction in patients with questionable or normal electrocardiograms, (2) proven myocardial infarction diagnosed by EKG or enzyme assay, (3) Progression or extent of the infarct in the above conditions.

TECHNICAL APPROACH

Patients with suspected or proven myocardial infarction will undergo myocardial scanning upon request of the Cardiology Service. Imaging will be performed at the bedside from 12 hours to six days after the onset of chest pain. The results will be compared to the clinical and laboratory findings to determine the accuracy and limitation of this technique in the diagnosis of myocardial infarction and its extent and progress if present.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$337
FY77	\$ -	-	-	-

PROGRESS

Tc-99m pyrophosphate for myocardial infarction imaging has been granted a New Drug Application by FDA and is now considered a well-established procedure by NRC. However, myoglobin radioimmunoassay appears to be much more sensitive and has largely replaced Tc-99m pyrophosphate myocardial infarction imaging in this institution.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Separation and Identification of CPK Isoenzyme by RIA Technique

WORK UNIT NO: 76/30

PRINCIPAL INVESTIGATOR: MAJ A. Hughes, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To develop a radioimmunoassay method for detecting creatine phosphokinase isoenzymes for diagnostic purposes as indicators of myocardial damage.

TECHNICAL APPROACH

New Zealand white rabbits will be injected with CPK isoenzymes to elicit antibody production. The isoenzymes will be radiolabelled and standard radioassay procedures will be performed to determine antibody-antigen interaction and specificity.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$2357	\$120	-	\$2475
FY77	4740	3000	-	\$7740

PROGRESS

Attempts to produce antibody were unsuccessful and the investigator has now departed.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Diagnostic Adrenal Scanning with ^{131}I (NP59)

WORK UNIT NO: 76/33

PRINCIPAL INVESTIGATOR: COL M L Nusynowitz, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The purpose of this study is to determine the usefulness of ^{131}I -NP59 in scanning of the adrenal glands. It will be employed for the following purposes: (a) As a screening test for detection of primary aldosterone tumor, Cushing's disease, adrenal cortical adenoma, or pheochromocytoma. (b) Imaging of adrenals in patients who require adrenal venography and are allergic to contrast media. (c) Detection of unilateral adrenocortical hypofunction: calcification, metastatic carcinoma, post-venography infarction, etc. (d) Detection of functioning adrenal remnant after adrenalectomy for Cushing's syndrome. (e) Aid in assessment of adrenocortical steroid therapy.

TECHNICAL APPROACH

Patients with clinical evidence of adrenal disease will be studied upon referral from the Endocrine Service. Adrenal imaging will be performed after injection of the material to assess the presence or absence of visualization of the adrenal glands, their size and response to suppression therapy.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$ 337	-	-	\$337
FY77	888	-	-	888

PROGRESS

A total of six patients have been studied to date. NP59 appears to be a satisfactory agent for adrenal imaging.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Liver Amylase: Fact or Fiction

WORK UNIT NO: 77/07

PRINCIPAL INVESTIGATOR: CPT L M Lehrner, MD

ASSOCIATE INVESTIGATORS: MAJ C M Lund, COL J L Pitcher, LTC J S Gunther

OBJECTIVES

The two objectives are: (1) to determine if human liver contains an α -amylase other than that contributed by "trapped" blood, (2) to determine if there is a detectable alteration in serum and/or urine total and amylase activity and/or amylase isozyme patterns in patients with liver disease.

TECHNICAL APPROACH

Routine laboratory examinations will be performed prior to each peritoneoscopy procedure. Depending on the clinical indications one or more liver biopsies will be obtained. A 5 mm core of liver tissue from each biopsy will be subjected to special assay, and accordingly the existence of liver amylase and alterations in serum and/or urine total amylase activity and/or amylase isozyme patterns in patients with histologically proven liver disease will be definitely proven or disproven.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$ 889	\$1000	-	\$1889

PROGRESS

Twelve patients have been studied to date and laboratory data is underway. We will decide if further patients need to be studied after analyzing data from these first 12 patients.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Efficacy of Sucralfate in the Treatment of Gastric Ulcer

WORK UNIT NO: 77/08

PRINCIPAL INVESTIGATOR: COL J L Pitcher, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To evaluate the efficacy of Sucralfate in the endoscopically measured healing of benign gastric ulcer.

TECHNICAL APPROACH

Patients with benign uncomplicated gastric ulcer will be treated with Sucralfate tablets for a maximum period of six weeks. Endoscopy will be performed at 0, 14, 28, and 56 days.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$889	-	-	\$889

PROGRESS

Two patients who were admitted to the study were withdrawn at the request of the sponsoring drug company due to a revision of the study protocol implemented by the company. The revised protocol has OTSG approval and patients are again being studied.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Use of 99m-Tc-Pyrophosphate Bone Scanning Agents in the Diagnosis
and Assessment of Myocardial Damage Secondary to Chemotherapeutic
Agents Used in Treatment of Cancer
WORK UNIT NO: 77/14

PRINCIPAL INVESTIGATOR: MAJ Alan D Hughes, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To correlate drug dosage, laboratory findings, histologic findings,
electron microscopic and cardiac scintigraphic findings in dogs.

TECHNICAL APPROACH

Adriamycin was administered in selected chronic dosages to beagles.
Serial cardiac scintigraphy and other laboratory tests were performed
on a weekly basis. Autopsy was performed upon the spontaneous death
of the dogs.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$4741	\$1819	-	\$6560

PROGRESS

Tc-99m pyrophosphate appeared to be a suitable agent for assessing
myocardial damage secondary to cancer chemotherapy. The principal
investigator has departed.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Radionuclide Angiocardiology Evaluation of Cardiopulmonary
Function Using a Mobile Dual Cardiac Probe

WORK UNIT NO: 77/16

PRINCIPAL INVESTIGATOR: MAJ Robert Sonnemaker, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To assess the clinical usefulness of a mobile dual cardiac probe in the assessment and serial evaluation of cardiopulmonary function in patients with acute, chronic or potential cardiopulmonary compromise.

TECHNICAL APPROACH

Patients admitted to the Intensive Care Units will be studied to determine left ventricular ejection fraction, pulmonary transit time, cardiac output, stroke volume, end-diastolic volume and pulmonary blood volume at bedside.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$ 889	-	\$6620	\$7509

PROGRESS

The mobile dual cardiac probe arrived during late August. Five patients have been studied to date, and satisfactory results have been obtained. Clinical efficacy will be evaluated at the end of the loan period of the probe.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Differentiation of Restrictive from Obstructive Lung Disease by
Comparing Parameters of Forced Expiratory Flow

WORK UNIT NO: 77/22

PRINCIPAL INVESTIGATOR: COL R C Zurek, MD; MAJ C R Beechler, MD

ASSOCIATE INVESTIGATORS: W.N. Schmidt-Nowara, MD

OBJECTIVES

To evaluate the necessity of performing static lung volumes in light of possible predictive value of the vital capacity and the forced expiratory volume at one second-vital capacity ratio.

TECHNICAL APPROACH

Data from patients who have received complete pulmonary function studies and on whom morphometric data have been gathered will be retrospectively analyzed to determine the predictive value of the vital capacity and the forced expiratory volume at one second-vital capacity ratio in the diagnosis of restrictive lung disease. Computerized data correlation will be performed at the University of New Mexico Medical School by Dr. Schmidt-Nowara

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$ 889	-	-	\$ 889

PROGRESS

Data collection has been completed and are currently being analyzed at the University of New Mexico Medical School by Dr. Schmidt-Nowara.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Evaluation of Selection Criteria for Entry to the 300-91C Program

WORK UNIT NO: 76/36

PRINCIPAL INVESTIGATOR: LTC L Hauck, ANC

ASSOCIATE INVESTIGATORS: CPT N Sass, PhD

OBJECTIVES

To determine factors suitable for course entry selection criteria which may be predictive of success or failure of students in the Clinical Specialist Course.

TECHNICAL APPROACH

A retrospective study of available data on students in previous 91C course is being conducted. Twenty variable factors are being correlated using a Manova computer program against each student's success or failure in the course, in an attempt to determine correlative predictors of success or failure.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$2357	-	-	\$2357
FY77	1778	-	-	1778

PROGRESS

The GT score and the California Achievement Tests in Math and Reading were found to be highly significant prospective indicators of a student's likelihood of successfully completing the 91C Course. A paper reporting the results of this study was submitted to Military Medicine. The results were also forwarded to the appropriate agencies at HSC, AHSUSA, and OTSG.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Umbilical Cord Lactate, Pyruvate, Betahydroxy Butyrate, pCO₂
pO₂, and pH Value in Normal and Abnormal Pregnancies

WORK UNIT NO: 74/01

PRINCIPAL INVESTIGATOR: COL A. Killam, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To study the effect of labor on normal pregnancies and pregnancies complicated by placental insufficiency.

TECHNICAL APPROACH

Maternal amniotic fluid, venous, umbilical arterial and umbilical venous blood samples will be studied for the above levels. The results will be correlated with neonatal outcome and morbidity.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$ 337	-	-	\$ 337
FY77	-	-	-	-

PROGRESS

No further work has been done since last report.

STATUS: Ongoing. Will terminate or resume sample collection during this FY.

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Inhibition of the Vascular Effect of Estrogen with Actinomycin D

WORK UNIT NO: 74/10

PRINCIPAL INVESTIGATOR: COL A. Killam, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if the uterine vascular effect of estrogens involves the same mechanism as the uterine growth promoting effect in dogs.

TECHNICAL APPROACH

The increased uptake of amino acids will be blocked with Actinomycin D and uterine blood flow will be measured to see if the Actinomycin D also blocked the increase in uterine blood flow in response to a standard injection of estrogen

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$ 337	-	-	\$337
FY77	-	-	-	-

PROGRESS

This study was merged with 77/19

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Maternal and Fetal Plasma Levels of Steroid Hormones in Normal and Pathological Pregnancies During Labor

WORK UNIT NO: 74/16

PRINCIPAL INVESTIGATOR: COL A. Killam, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if a rapid assay of steroid hormones would be of clinical value if drawn at the onset of labor from maternal vein or fetal scalp.

TECHNICAL APPROACH

Women in labor with a high risk for fetal distress from placental insufficiency will be included as samples upon admission to Labor and Delivery. The radioimmunoassay for estriol is being modified by eliminating some steps and increasing the temperature during incubation.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip. Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$1680	-	-	\$1680
FY77	888	\$ 341	-	1229

PROGRESS

Initial phases have been completed with publication of papers as listed in previous year's report.

STATUS: Ongoing.

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Prostaglandin E₂, Efficacy Study for Termination of Pregnancy with Fetal Intrauterine Death, Missed Abortion or Hydatidiform

WORK UNIT NO: 75/09

PRINCIPAL INVESTIGATOR: COL W. Scragg MD

ASSOCIATE INVESTIGATORS: COL D. Boyce, M.D.

OBJECTIVES

To study the effect of Prostaglandin E₂ in vaginal suppository form to effect evacuation of products of conception in cases of fetal death in utero, hydatidiform mole and missed abortion.

TECHNICAL APPROACH

Hematological, urine and blood chemistries are evaluated three times during the treatment as well as vital signs. Suppositories are utilized as frequently as every two hours if needed.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$337
FY77	888	\$341	-	\$1229

PROGRESS

A total of 29 patients have now been treated by Prostaglandin E₂ suppositories. This method of management of intrauterine death and hydatidiform mole appears to be effective with minimal side effects. The data at this point has been collected but not completely collated. The Upjohn Company has terminated its efficacy study of the Prostaglandin E₂ vaginal suppositories. The drug has been approved by the FDA and is now commercially available.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Effect of Uterine Blood Flow on Placental Transport

WORK UNIT NO: 76/17

PRINCIPAL INVESTIGATOR: COL A. Killam, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine how altering uterine blood flow affects placental transport of different metabolites.

TECHNICAL APPROACH

Measure uterine blood flow by electromagnetic flow probe and placental transport by Fick principle, then reduce flow with a mechanical noose and repeat placental transport measurements.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$2357	-	\$3820	\$6175
FY77	\$6519	\$2900	-	\$9419

PROGRESS

Completed except for data evaluation. Fourteen sheep experiments were done. Data obtained showed erratic results. The animal preparation was very difficult technically. The equipment purchased is currently being utilized on Protocol 77/19.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Protein Supplementation of the Diets of Women with Positive Supine Hypertensive (Roll-Over Tests)

WORK UNIT NO: 76/19

PRINCIPAL INVESTIGATOR: MAJ Phillips

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To see if protein supplementation would reduce the incidence and severity of toxemia.

TECHNICAL APPROACH

Control or test diet would be given to pregnant teenagers with positive roll-over tests.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$673	-	-	\$673
FY77	-	-	-	-

PROGRESS

Preliminary tests show that (1) the incidence of toxemia is very low in our population; (2) the incidence of toxemia with a positive roll-over test is so low that it would take too many test subjects to see a difference in the treated and the control. The time involved would be too great to complete the study in sufficient time with the clinical personnel available.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Comparison of Clinical and Laboratory Measurements of Gestational Age to the Actual Gestational Age as Determined by Last Ovulation
WORK UNIT NO: 76/20

PRINCIPAL INVESTIGATOR: COL David Boyce, MD

ASSOCIATE INVESTIGATORS: COL Allen Killam, MD; MAJ Frank Bowen, MD;
MAJ R. Hanson.

OBJECTIVES

To test the reliability of clinical and laboratory methods of gestational age assessment by comparing the assessments to true gestational age as determined by basal body temperature curves defining last ovulation.

TECHNICAL APPROACH

Patients volunteering to record basal body temperatures prior to conception will be monitored throughout their pregnancy by serial sonography and serum estriols. The neonate will be evaluated for gestational age both in blinded and unblinded studies.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$337
FY77	-	-	-	-

PROGRESS

The study is still in the very early stages with only nine patients having either completed the study or presently undergoing evaluation. It is presently felt that at least two to three years will be needed to collect enough data to be significant.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Estriol Production Rate Studies in Pregnant Women

WORK UNIT NO: 76/29

PRINCIPAL INVESTIGATOR: LTC LL Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

Determination of estriol production rates in normal pregnant women and correlation in abnormal gestations with the clinical outcome.

TECHNICAL APPROACH

Estriol production rates will be estimated by the infusion of deuterated estriol into these women followed by subsequent serum sampling. A measurement of the amount of deuterioestriol present in extracted estriol samples relative to the total amount of estriol extracted would indicate the rate of endogenous estriol synthesized by the patient.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$ 337	-	-	\$ 337
FY77	-	\$80	-	80

PROGRESS

Samples from one patient have been submitted to the Collaboratory Institution, the University of Colorado, for analysis. The University cannot assist us with any patients until they receive renewal of their funding. Although several months have elapsed the protocol will be kept open in anticipation of further cooperation.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Correlation of Amniotic Fluid Cortisol and the Free Estriol
Surge in Maternal Plasma

WORK UNIT NO: 76/34

PRINCIPAL INVESTIGATOR: LTC L L Penney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To confirm the amniotic fluid cortisol levels of the study mentioned above. To correlate these levels with the maternal free estriol surge and the amniotic fluid L/S ratio and attempt to determine if the cortisol increase is also nonlinear and, if so, if it precedes or follows the free estriol surge.

TECHNICAL APPROACH

The amniotic fluid cortisol concentration and L/S ratios on each specimen submitted will be determined, as will plasma free estriol and cortisol when each amniocentesis is performed. The indications for amniocentesis will be based on currently accepted clinical criteria and the decision for the procedure will be made by attending and resident staff managing the patient. The analyses will be done by radioimmunoassay and TLC as presently performed in the RIA laboratories. The data will be subjected to regression analysis and appropriate rank correlation.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$ 673	-	-	\$673
FY77	888	\$841	-	1729

PROGRESS

Sixty-two study specimens have been analyzed and the data organized for presentation at the Armed Forces District Meeting of the American College of Obstetrics and Gynecology in October 1977. More patients are being studied.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Correlation of Choline Phosphotransferase Activity in Human Amniotic Fluid and Neonatal Nasopharyngeal Aspirates

WORK UNIT NO: 76/35

PRINCIPAL INVESTIGATOR: MAJ J B Haddock, MD; COL A. Killam, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To construct normograms of the activity of choline phosphotransferase in human amniotic fluid with respect to gestational age and activity of the enzyme in neonatal nasopharyngeal secretions at 6 hour intervals from birth. These levels will be related to the occurrence of idiopathic respiratory distress syndrome in the neonate. The ultimate objective is to determine whether this enzyme activity is a better predictor of idiopathic respiratory distress syndrome than the currently used lecithin/sphingomyelin ratio.

TECHNICAL APPROACH

Concurrent with otherwise medically indicated amniocentesis, 10 milliliters of amniotic fluid will be obtained and analyzed for choline phosphotransferase and phosphatidate phosphohydrolase activities. A normogram of enzyme levels with respect to gestational age will be constructed. These levels will then be correlated with the occurrence of idiopathic respiratory distress syndrome to see indeed if one or both are better predictors of the syndrome. Additionally, routine nasopharyngeal suction material will be collected at 6-hour intervals on neonates and analyzed for this enzyme activity. Levels of activity will be compared to the course of the disease in hopes of developing an objective technique for differentiating idiopathic respiratory distress syndrome from other causes of respiratory distress in the neonate.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$2357	\$ 950	-	\$3300
FY77	\$6519	2900	-	\$9419

PROGRESS

Amniotic fluid levels in uncomplicated pregnancies have been reported at the Armed Forces District of the American College Obstetrics and Gynecology meeting. A paper has been accepted for publication in Pediatric Research.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

Efficacy Study of (15S)-15 methyl Prostaglandin F2 α
TITLE: methyl ester Contained in a Silastic Intravaginal Device for
the Voluntary Termination of Human Pregnancy.
WORK UNIT NO: 77/01

PRINCIPAL INVESTIGATOR: COL D.C. Boyce, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

This study is designed to test the efficacy of a 15 methyl PGF2 α impregnated silastic device, placed intravaginally, as vehicle for the delivery of PG in effecting voluntary interruption of pregnancy.

TECHNICAL APPROACH

The Upjohn Company removed the silastic device prior to the initiation of this study.

FUNDING: None

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Ultrastructure Investigation of Prostaglandin and their Precursors
in the Human Fetal Chorioamniotic Membrane

WORK UNIT NO: 77/02

PRINCIPAL INVESTIGATOR: MAJ W C Daniell

ASSOCIATE INVESTIGATORS: B.E.F. Reimann

OBJECTIVES

To determine the subcellular location of prostaglandins and precursors in fetal amniochorionic membranes.

TECHNICAL APPROACH

Ultrastructure of fetal membranes have been observed.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$ 889	\$340	-	\$1229

PROGRESS

Have had difficulty obtaining a good water soluble embedding media so that lipids could be retained in tissue without use of osmium for fixation. At present we are attempting to react antibodies and peroxidase in thin sections of membrane prior to embedding of tissue and thereby circumvent this problem. Awaiting arrival of chemicals for use in indirect antibody labeling.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Prevention of Post-Cesarean Section Infections

WORK UNIT NO: 77/03

PRINCIPAL INVESTIGATOR: MAJ J. Haddock, MD; COL A. Killam, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To see if postoperative morbidity can be prevented with prophylactic antibiotic therapy.

TECHNICAL APPROACH

Placebo and two treatment regimens will be given in randomized double blinded fashion. Postoperative febrile morbidity will be compared within the two groups.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$178	-	-	\$178

PROGRESS

Awaiting final approval prior to instituting protocol.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Inhibition of Premature Labor with Terbutaline

WORK UNIT NO: 77/04

PRINCIPAL INVESTIGATOR: COL A. Killam, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To determine if the vascular effect of estrogen employs the same pathways as the growth promoting effect of estrogen on the sex organs of dogs.

TECHNICAL APPROACH

Actinomycin D will be given to dogs in sufficient dosage to block the growth promoting effect of estradiol 17-beta, which is a potent vasodilator of the uterus as well as a potent growth promoter. If the vascular effect of estradiol-17-beta is not affected nearly as much as the growth promoting effect, this would indicate that the vascular effect does not rely on transcription of a message from nuclear chromatin to messenger R.N.A.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$ 356	-	-	\$ 356

PROGRESS

Final approval obtained from SGO and FDA. Placebo and treatment doses being prepared by Pharmacy. Will begin series during October 1977.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Study to Determine the Ability of Amniotic Fluid to Inhibit Growth
of E. Coli

WORK UNIT NO: 77/06

PRINCIPAL INVESTIGATOR: COL David Boyce, MD

ASSOCIATE INVESTIGATORS: MAJ M. Sellers, PhD; COL Allen Killam, MD

OBJECTIVES

To determine the inhibitory effects of the amniotic fluid on the growth of E. coli and the relationship of zinc and phosphate to this inhibition.

TECHNICAL APPROACH

The growth and/or inhibition of a laboratory strain of E. Coli in amniotic fluid as well as certain controlled media is to be monitored by a technique using ^{14}C tagged glucose in the various culture media and monitored by the amount of $^{14}\text{CO}_2$ eluted as measured in a liquid scintillation counter. Maternal and cord blood serum zinc levels will be determined as well as the zinc and phosphate ratios of the amniotic fluid. An attempt will be made to correlate the inhibitory or noninhibitory effect of amniotic fluid on the E. Coli as well as the Zinc and zinc/phosphate ratios to this inhibitory effect to neonatal sepsis.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$6519	\$2900	\$14,989	\$24,408

PROGRESS

It has been determined at this point that any production of $^{14}\text{CO}_2$ produced by bacterial metabolism can be used to monitor bacterial growth. We are presently involved in determining if this method will show growth inhibition by amniotic fluid. As soon as the laboratory technique has been worked out we will be ready to begin to apply it clinically.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Effect of Prostaglandin Synthesis Inhibitors on Uterine
Blood Flow

WORK UNIT NO: 77/19

PRINCIPAL INVESTIGATOR: MAJ Walter C Daniell, MD

ASSOCIATE INVESTIGATORS: B.E.F. Reimann, MSc COL A. Killam, MD

OBJECTIVES

To study the effect of prostaglandin synthesis inhibitors by direct
flow-pressure measurements in both iliac artery and iliac vein in ewes.

TECHNICAL APPROACH

Pregnant and nonpregnant sheep will have blood flow monitors implanted
around the two uterine arteries and catheters placed in the femoral
artery and vein. A variety of substances will be infused to determine
their effect on uterine blood flow, including arachidonic acids,
prostaglandin synthesis intermediates, prostaglandins, known blockers of
prostaglandin synthesis, and drugs of unknown efficacy in blocking
prostaglandin synthesis.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$4741	\$2600	-	\$7341

PROGRESS

Have just received license for cannabinoids which are currently on order.
Uterine flow probes have been placed on seven pregnant dogs and technical
problems and surgical techniques have been worked out. Aspirin and indo-
methacin have been given orally to these animals and no change in uterine
blood flow has been noted.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Efficacy Study of (15S)-15-methyl Prostaglandin F2a (tham) (U-32,921E)
for Abortifacient Activity by IM, Administration in Cases of Failed
Abortion by Other Means

WORK UNIT NO: 77/23

PRINCIPAL INVESTIGATOR: COL Warren N. Otterson, MD

ASSOCIATE INVESTIGATORS: COL David Boyce, MD; COL A. Killam, MD

OBJECTIVES

To determine the efficacy of (15S)-15-methyl Prostaglandin F2a (tham) as an abortifacient by IM administration for failed second trimester abortion following intra-amniotic injection of Prostaglandin.

TECHNICAL APPROACH

Patients desiring second trimester abortion will be counselled and selected for this study following their signing of a voluntary agreement to participate in this study. Forty milligrams of Prostaglandin F2a will be injected intra-amniotically. If this method fails to accomplish the second trimester abortion within 24 hours, the intramuscular 15 methyl Prostaglandin F2a will be administered according to protocol. Hemagram, urinalysis, clotting studies and vital signs will be monitored prior to, during, and at the termination of the abortion.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$ 178	-	-	\$178

PROGRESS

The paperwork has been accomplished and approved. We are presently waiting for the investigational drug to be supplied by the Upjohn Company. At present, no patient has been entered into the study.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: A Comparison of Phospholipid Levels and Choline Phosphotransferase
(CPT) Activity in Amniotic Fluid and Newborn Tracheal Fluid

WORK UNIT NO: 77/25

PRINCIPAL INVESTIGATOR: COL A. Killam, MD

ASSOCIATE INVESTIGATORS: LTC L L Penney; MAJ L Cheldelin; MAJ R Heath

OBJECTIVES

To determine if the level of phosphatidyl glycerol (PG) and phosphatidyl inositol (PI) on the activity of choline phosphotransferase could serve as an accurate index of lung maturity.

TECHNICAL APPROACH

Amniotic fluid, and neonatal gastric and pharyngeal fluids which are normally discarded, will be analyzed for phosphatidyl glycerol, phosphatidyl inositol, choline phosphotransferase, and magnesium. The levels measured will be correlated with the incidence and severity of neonatal respiratory stress and hyaline membrane disease.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$4741	\$2800	-	\$7541

PROGRESS

Combined with 76/35. Basic biochemical analysis is being worked out. Sample analysis will begin within one or two months unless further technical difficulties are encountered. A paper was presented by Dr. Haddock on CPT as a marker of gestational age at the Armed Forces District American College of Ob-Gyn in September 1976 and won the Host Award for best clinical paper in Ob-Gyn.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Fetal Movement as an Indicator of Fetal Well Being

WORK UNIT NO: 77/26

PRINCIPAL INVESTIGATOR: MAJ Walter Daniell, MD

ASSOCIATE INVESTIGATORS: COL A. Killam, MD; MAJ T F Howard, MD

OBJECTIVES

To determine if quantitation of fetal movement is a reliable indicator of fetal well-being comparable to estriols and the oxytocin challenge test.

TECHNICAL APPROACH

Patients admitted to the Antepartum OB Ward who are being monitored by estriols and oxytocin challenge tests will be asked to participate in this study. They will be instructed to count and record the number of fetal movements that they feel each hour between 0800 hours and 2200 hours. Changes noted in fetal movement will then be compared with changes in the estriols, the OCT, and the ultimate fetal outcome to determine if changes in the number of fetal movements is a predictor of intrauterine fetal distress that could be comparable to or better than present methods being used. Fetal movements counted each day will be compared to those counted each hour to determine if shorter time periods for counting fetal movements would be of value.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$ 356	-	-	\$ 356

PROGRESS

Awaiting approval from OTSG.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Molecular Etching

WORK UNIT NO: 70/111

PRINCIPAL INVESTIGATOR: B.E.F. Reimann, DSc

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To obtain general information on the ultrastructure of biological membranes (in particular the erythrocyte membrane) and other cellular organs in order to discern their structural changes under varying experimental (and disease related) conditions and, for this reason, to develop techniques by which the biological material can be investigated in the least altered state employing methods such as freeze drying and ionic etching in conjunction with electron microscopy.

TECHNICAL APPROACH

The final goal is to subject lyophilized embedded biological material to a bombardment with accelerated ions or atoms and to reveal the obtained structures by electron microscopy. Presently the experiments are primarily concerned with osmotic pressures of erythrocytes employing freezing point depression osmometry and direct measurements with a Pfeffer's cell. A "critical point" drying chamber has been constructed.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$ 337	-	-	\$ 337
FY77	888	\$340	-	\$1228

PROGRESS

Experiments on Flavobacterium dehydrogenans revealed a reduction of more than 10% in the membrane diameter upon exposure to light. A paper has been submitted discussing these results. Additionally, various polymer forming substrates for embedding lyophilized cell material for electron microscopy have been prepared and are currently being tested.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Injected Marihuana: Effects of Cannabinol

WORK UNIT NO: 71/38

PRINCIPAL INVESTIGATOR: B.E.F. Reimann, DSc

ASSOCIATE INVESTIGATORS: Eleanor Duke, PhD

OBJECTIVES

To determine the possible toxic effect of intravenously injected cannabinoids in aqueous decoctions of marihuana.

TECHNICAL APPROACH

The project uses the Duquenois-Neum reaction modified by Lewin, thin layer chromatography and gas-liquid chromatography to determine amounts of cannabinoids in aqueous and other extractions.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$ 337	-	-	\$ 337
FY77	-	-	-	-

PROGRESS

No progress. Lack of raw material.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: An Evaluation of Choline Phosphotransferase (CPT) in Newborn
Cord Blood, Amniotic Fluid and Pharyngeal Secretions

WORK UNIT NO: 74/23

PRINCIPAL INVESTIGATOR: MAJ F Bowen, MD

ASSOCIATE INVESTIGATORS: CPT N.L. Sass, PhD

OBJECTIVES

To measure choline phosphotransferase in cord blood, amniotic fluid and pharyngeal secretions and compare measurements to the clinical presentation of Hyaline Membrane Disease.

TECHNICAL APPROACH

Collect amniotic fluid from routine amniocentesis. Collect cord blood and pharyngeal secretions from infant at delivery. Collect lung tissue from autopsy and primates to standardize technique.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$2357	-	-	\$2357
FY77	-	-	-	-

PROGRESS

All investigators involved with this protocol have departed. The productive aspects are being continued under protocols 76/17 and 77/25.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: A Single Blind Study to Determine the Effects of Corticosteroids on
Subsequent Developments of Infants Subjected to Severe Intrapartum
Asphyxia

WORK UNIT NO: 74/47

PRINCIPAL INVESTIGATOR: MAJ F. Bowen, MD

ASSOCIATE INVESTIGATORS: MAJ D.F. Turbeville MD; CPT R.E. Heath, MD

OBJECTIVES

To assess the effect of steroids on subsequent development in asphyxiated infants as measured by the Bayley Infant Developmental Test.

TECHNICAL APPROACH

This study will be conducted in a single blind fashion. A psychologist with no previous knowledge of the case histories of the patients entered into the study will administer the Bayley Test. From the results of this test he will attempt to ascertain indications of previous incidents of asphyxia and/or steroid treatment to prevent or reverse the effects of asphyxial states.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$337
FY77	-	-	-	-

PROGRESS

Difficulties in obtaining psychological testing and departure of the investigators has caused termination of this project.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Arterial-Venous Amino Acid Gradients in Rhesus Monkey Infants
Receiving Total Intravenous Alimentation

WORK UNIT NO: 75/02

PRINCIPAL INVESTIGATOR: MAJ Frank Bowen, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The study is designed to determine the A-V gradients of the various amino acids across the brain in infant monkeys receiving intravenous amino acids.

TECHNICAL APPROACH

Infant rhesus monkeys (maintained in Armstrong heaters) will be studied from Day 2 to Day 5 postpartum. Forty-eight hours IV infusions through the lateral jugular vein will be performed using 10-15% dextrose or that amount necessary to maintain the blood glucose between 80-120 mg%. The infusate will contain 2 gms/kg of amino acid hydrolysate (Freeamine) and will be run at 100 cc/kg per day. Blood glucose, pH, urine output, specific gravity, urine glucose and protein will be measured daily. Forty-eight hours after infusion, 5 cc of blood will be aspirated from the jugular vein. This will be sent out for amino acid analysis. On Day 5 the animal will be sacrificed and autopsied.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$1683	-	-	\$1683
FY77	-	-	-	-

PROGRESS

Breeding difficulties forced cancellation of this project. The investigator has also departed.

STATUS: Terminated

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE:Chemotherapy of Cancer

WORK UNIT NO: 76/07

PRINCIPAL INVESTIGATOR:Dr. J. Swaney, M.D.

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The association of William Beaumont Army Medical Center's Pediatric Oncology and Hematology Service with the various members of the Southwest Cancer Chemotherapy Study Group, Pediatric Division (through M.D. Anderson Hospital and Tumor Institute), Acute Leukemia Group B, and with the Children's Hospital Oncology Center, Denver, Colorado, in conducting trials of chemotherapy in cancer will (1) obtain the necessary understanding of the cancer process; (2) determine effective therapeutic approaches; and (3) provide needed information to use in the care of children with malignant diseases. The association provides for probing of common knowledge and for better statistical evaluation of processes and results.

TECHNICAL APPROACH

Each protocol used by the various aforementioned groups goes through a rigorous process of review, revision, and evaluation prior to becoming activated for group usage. The flow of protocol from author through specific disease committee, statistician, committee headquarters, studies management board, Cancer Investigation Branch of the National Cancer Institute is usual process. Data collected by each member is reviewed and analyzed by the individual data sent.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip,Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$337
FY77	-	-	-	-

PROGRESS

The patients on the noted protocols continue as previously. The patients remain in continuous remission. The patient on Denver Children's AL#3 HR has discontinued chemotherapy and is presently NED.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Echocardiographic Assessment of Congestive Heart Failure in
Premature Infants with Respiratory Disease

WORK UNIT NO: 76/22

PRINCIPAL INVESTIGATOR: MAJ Heath, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare and evaluate different techniques for assessing congestive heart failure.

TECHNICAL APPROACH

We are continuing to evaluate newborns at birth and follow them serially with echocardiograms until they are asymptomatic.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$674	-	-	\$674
FY77	888	-	-	888

PROGRESS

The results of this study have been submitted for publication. Criteria were developed which predicted with 100% accuracy the occurrence of neonatal congestive heart failure by assessing the physical dimension of the heart with respect to ECG findings.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Use of Elliott's B Solution, Sterile as Methotrexate
Diluent for Intrathecal Use

WORK UNIT NO: 76/28

PRINCIPAL INVESTIGATOR: Dr. J Swaney, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

The object of this study is to determine if the use of Elliott's B solution as diluent for intrathecal Methotrexate will reduce the evidence of side effects, i.e., headaches, fever, vomiting, etc.

TECHNICAL APPROACH

Patients are eligible for this study who are receiving intrathecal Methotrexate either as prophylaxis or for treatment of central nervous system leukemia. Stock solutions of Methotrexate will be diluted to a concentration of 1 mg/cc with Elliott's B solution. The dose of Methotrexate shall be calculated at 12 mg/M² per dose with a maximum of 15 mg/M² per dose. The timing of the intrathecal injection shall be individually determined. Records shall be kept of patient status following injection as regards headache, fever, nausea, vomiting, etc. Response shall be determined by absence of side effects or their diminution if they had been previously present. Possible CNS contamination from injection of foreign material may result in toxicity which may be evidenced by fever, headache, nausea, and/or vomiting following intrathecal injection of Methotrexate diluted with Elliott's B solution. Approximately 10 patients per year will be treated on this protocol.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$ 337	-	-	\$337
FY77	-	-	-	-

PROGRESS

Investigator has been absent from William Beaumont Army Medical Center for the past year. Presently plans are underway to re-activate the protocol.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Comparison of Pneumatic Otoscopy and Impedance Tympanometry in
the Follow-up of Otitis Media in Children

WORK UNIT NO: 76/37

PRINCIPAL INVESTIGATOR: Richard M. Lampe, MD

ASSOCIATE INVESTIGATORS: MAJ L.V. Cheldelin, MD, L. Artalejo, DAC, CPT
Neil L. Sass, MSC

OBJECTIVES

To compare pneumatic otoscopy with impedance tympanometry in the followup of otitis media and to assess the efficacy of three medical regimens in the treatment of acute otitis media.

TECHNICAL APPROACH

In cross sectional studies, impedance tympanometry is a reliable screening method for the detection of middle ear fluid in the pediatric age group and compares favorably with pneumatic otoscopy in accurately detecting middle ear fluid. Impedance tympanometry offers an objective measurement of middle ear fluid and its sequential presence or absence following acute otitis media. Comparison of these two methods in the followup of middle ear effusion should demonstrate the utility of impedance tympanometry in the followup of middle ear effusions.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY77	\$ 200	-	-	\$200

PROGRESS

To date 20 patients have been enrolled in the study and ten of these have completed their participation. Due to the double blind nature of the study, the data have not been analyzed rigorously. However, it does appear that the tympanometric readings have been in excellent agreement with the pneumatic otoscopy. If subsequent statistical analysis indicates that the correlation is indeed good, impedance tympanometry promises effective utilization of the technique in objectively evaluating the patient's progress when treated with varying drug regimens. Additionally, tympanometry in the hands of a skilled technician could release physicians from routine post-ear infection followup.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Detection of Bacterial Antigen in Body Fluid by Counterimmuno-electrophoresis

WORK UNIT NO: 77/05

PRINCIPAL INVESTIGATOR: LTC R. Lampe, MD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To compare the presence of bacterial antigen in various body fluids detected by counterimmunoelectrophoresis (CIE) to standard bacteriologic methods of identification.

TECHNICAL APPROACH

Pediatric patients suspected of having a bacterial infection will have appropriate Gram stains and cultures performed. In addition, sera, urine, and the body fluid suspected of being infected will be studied using CIE with the following antisera: Pneumococcal antisera, Hemophilus influenza B antisera, Neisseria meningitidis antisera and Staphylococcal antisera. Should a specific antigen be detected, this will be followed sequentially during the hospitalization. The withdrawal of body fluids for this study will only accompany clinically indicated procedures requiring fluid withdrawal for diagnostic purposes.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY77	<u>\$2614</u>	<u>\$2580</u>	<u>-</u>	<u>\$5,194</u>

PROGRESS

Over 200 clinical specimens (CSF, serum, urine, plural fluids, exudates) have been analyzed to date, with the specimens from 10 individual patients diagnosed as positive by CIE. Eight of the ten patients had bacteriologic cultures confirmatory of the CIE diagnosis of pneumococcus, H Flu B, or Streptococcus B. Bacteriologic cultures were negative in the other two patients. Strep A can be detected, but it has not appeared in any clinical specimens as yet. Not only is the CIE technique much more rapid (1 hour versus 24 hours for cultures), but it can detect the presence of antigen even after antibiotic therapy has caused cultures to become negative.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Zinc Levels in Maternal Infant Pairs

WORK UNIT NO: 77/10

PRINCIPAL INVESTIGATOR: MAJ L V Cheldelin, MD

ASSOCIATE INVESTIGATORS: COL A. Killam, MD

OBJECTIVES

To determine the zinc level in maternal-infant pairs and to see if there is a correlation with incident infection.

TECHNICAL APPROACH

Zinc and phosphate concentrations in maternal and neonatal cord blood will be correlated with the incidence of neonatal sepsis in a blind retrospective study. The hypothesis of increasing zinc and phosphate levels in enhanced amniotic fluid bactericidal activity will be studied.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY77	\$4740	\$3000	\$14,989	\$22,729

PROGRESS

The atomic absorption spectrophotometer was procured during late September 1977 and shakedown of analytical techniques began. Data collection will begin during October 1977.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

Relationship of Anterior Fontanelle Size and Transillumination
TITLE: Finding of the Newborn

WORK UNIT NO: 77/11

PRINCIPAL INVESTIGATOR: MAJ L V Cheldelin, MC

ASSOCIATE INVESTIGATORS: MAJ R E Heath, MD; CPT J R Ramsey, MD

OBJECTIVES

To evaluate the effect of anterior fontanelle size in the interpretation of transillumination measurements of the newborn skull.

TECHNICAL APPROACH

Newborns will be transilluminated with a Chun Gun and fontanelle size will be measured using a series of concentric centimeter circles. Transillumination values will be correlated with gestational age to evaluate Swick's hypothesis that anterior fontanelle size had no statistical significance on the area of transillumination.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$178	-	-	\$178

PROGRESS

Preliminary data did not support Swick's report of increasing transillumination with increasing gestational age.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Investigation of the Effects of Diphenylhydantoin on Intellectual Functioning of Children

WORK UNIT NO: 77/13

PRINCIPAL INVESTIGATOR: LTC P F LoPiccolo, MD

ASSOCIATE INVESTIGATORS: CPT Robert Hulsebus, PhD

OBJECTIVES

To determine if Dilantin has any effect on intellectual functioning.

TECHNICAL APPROACH

To test children over the age of six years who have been placed on phenobarb or dilantin because of a new seizure disorder. To test children who have been on long term anticonvulsants to see if there has been any change in intellectual function. This can only be accomplished if children had educational and psychological evaluations before the onset of their seizure disorder. Testing is being accomplished in Psychology using the WISC-R. The first part of the study has gone slowly because we have had very few cases of new spontaneous seizure disorders in children over the age of 6 years. We have two patients on the study so far, and the one who has completed all the testing shows some interesting, unexplained findings. We have collected a number of cases for the second part of the study, but testing has not been accomplished because of lack of personnel and the ability to pay someone to test these children. Progressing slowly and would like to continue, but will need more time.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	<u>\$ 178</u>	-	-	<u>\$178</u>

PROGRESS

Due to the low incidence of spontaneous seizure disorders in the study population, only two patients have been admitted to the first portion of the study. The one child who has completed the study exhibited interesting, unexplained findings. A number of patients have been admitted to the second portion of the study, but testing has not yet begun due to lack of personnel and funds.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: The Infant Parent Bonding and Its Relationship to the Healthy
Resolution of Grief

WORK UNIT NO: 77/18

PRINCIPAL INVESTIGATOR: CPT J R Ramsey, MD

ASSOCIATE INVESTIGATORS: Sue Weider, Social Worker, Vivian Sheliga, LT MSC

OBJECTIVES

To evaluate our current inpatient and outpatient nursery services and to increase our help to families who experience the death of a newborn. We were particularly interested in how absence of "normal" bonding affects the grief reaction.

TECHNICAL APPROACH

Eighteen families were interviewed, half in hospital, half in homes. Two interviewers of the three on the team saw each family. Interviews were geared to a specific set of questions and all were taped when permission was given by family. Family previously had been asked to complete a brief questionnaire containing some of same questions as interview.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$ 889	-	-	\$889

PROGRESS

Many factors have been delineated as contributing to the prolongation of parental grief following the death of a newborn, with most of the factors identifiable as areas which more sensitive hospital personnel could help alleviate. Data are currently awaiting analysis; but already some of the millenary findings are being incorporated by our social workers into routine operational guidelines.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Breast-Feeding Survey

WORK UNIT NO: 77/21

PRINCIPAL INVESTIGATOR: CPT M.A. Nelson, ANC

ASSOCIATE INVESTIGATORS: CPT Jackson ANC MAJ L Cheldelin, MD

OBJECTIVES

Evaluate effectiveness of current breast feeding-teaching program at this hospital. Determine breast feeding population and reasons for decision to do so.

TECHNICAL APPROACH

Mothers visiting the Well Baby Clinic will be administered a questionnaire on several successive visits to determine the number of breast feeding mothers, non-breast feeding mothers and/or discontinued breast feeding mothers. Data will be analyzed attempting to identify factors which encourage or discourage mothers from breast feeding.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$178	-	-	\$178

PROGRESS

Due to staffing problems and a backlog of patients being seen in the Well Baby Clinic, proper procedure for administration of questionnaire was not being followed. Rather than continue to haphazardly conduct the survey and obtain results of no validity, the administration of the survey has been suspended. The forms have been kept for use at a later date. At present all that has been done is to collect a small sampling of responses, the results of which would be insignificant in themselves.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Assessment of Psychological Involvement in Patients Presenting with
Back Problems

WORK UNIT NO: 75/29

PRINCIPAL INVESTIGATOR: MAJ Frank H. Rath, Jr.

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To improve psychological assessment procedures using the MMPI with patients presenting with low back problems and better define those MMPI profiles reflecting premorbid personality dispositions which contraindicate medical/surgical intervention of low back pain syndromes.

TECHNICAL APPROACH

All outpatients in the Orthopedic Clinic presenting with low back pain which meet the criteria will be requested by the attending physician to complete the MMPI, until a sample size of 500 completed MMPI profiles are obtained. This should take approximately 12 months (the present rate of such patients is estimated at 30-50 per month). All in-patients on Orthopedic wards scheduled for either conservative treatment of low back problems or surgery (spinal fusion or dissection) will be administered the MMPI.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$ 674	\$300	-	\$974
FY77	\$ 888	-	-	888

PROGRESS

Sample size of 150 obtained for initial data. Followup evaluations have been obtained on 26 patients and preliminary data analyzed. Followup will be made on an additional 30 patients, at a minimum, by 1 March 1978. Some difficulty has been encountered in locating patients.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Infant Auditory Discrimination of Parents and Strangers

WORK UNIT NO: 77/12

PRINCIPAL INVESTIGATOR: CPT R C Hulsebus, PhD

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To assess the newborn infant's abilities to recognize their parents by voice discrimination and to determine if infants' reactions to their fathers' are different from those of a male stranger.

TECHNICAL APPROACH

Infants are tested about two weeks after birth in their homes according to the guidelines suggested by the review committees involved. Following tape recordings of infants' crying patterns, there are reliability checks carried out by two raters for the various measures utilized. The results will be presented at either regional or national scientific meetings.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$889	-	\$1862	\$2751

PROGRESS

Over half of the infants have been tested; the remainder will be tested by the first of the year (1978) and the report submitted around that time.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Compartmental Pressure Studies of the Legs of Traumatized Patients

WORK UNIT NO: 76/04

PRINCIPAL INVESTIGATOR: CPT J.C. Wright, MC

ASSOCIATE INVESTIGATORS: COL R J Bagg, MC

OBJECTIVES

To study the inter compartmental pressures of the anterior and posterior compartments of legs of at least 5 but not more than 25 patients following disease or injury and comparing these pressures with two groups of normal volunteers and volunteers following strenuous physical activity. These intercompartmental pressure values will be correlated with the clinical picture in cases of disease or injury (increasing circumference, pain, decreased spot or activity or sensation, and quality of distal pulses), and subsequent treatment of these extremities will be made without regard to values of the pressure study. A determination will be made as to whether intercompartmental pressures offer significant advantage in determining the need for fasciotomy over known clinical parameters.

TECHNICAL APPROACH

An 18 gauge needle will be inserted into the anterior and posterior compartments of the leg following a sterile preping of the area. The technique of recording intercompartmental pressure will be the same as described by Whiteside in 1975. Upon completion of the study, the compartmental pressure obtained will be correlated with the clinical picture.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$337	-	-	\$337
FY77	178	-	-	178

PROGRESS

The investigators have departed. After finding normal studies in the preliminary patients the study has not been continued.

STATUS: Completed

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Post Traumatic Hepatic Dysfunction Study

WORK UNIT NO: 76/08

PRINCIPAL INVESTIGATOR: MAJ Hartong, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To ascertain the etiology and pathophysiology of patients admitted to the Trauma Center who develop post-traumatic hepatic dysfunction.

TECHNICAL APPROACH

Liver chemistries are performed on a scheduled basis on patients admitted with criteria developed for the study which basically consists of severe shock and multiple injuries other than liver. Liver biopsies are done on those individuals who exhibit chemical evidence of hepatic dysfunction.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$ 674	-	-	\$674
FY77	\$ 178	-	-	178

PROGRESS

Due to the limited number of patients meeting the pre-established criteria for entry into the study very few patients have been entered.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Development of a Computerized Trauma Registry

WORK UNIT NO: 76/09

PRINCIPAL INVESTIGATOR: MAJ Hartong, MC

ASSOCIATE INVESTIGATORS:

OBJECTIVES

To develop a computerized trauma registry for data recall on all patients admitted to the Trauma Center.

TECHNICAL APPROACH

A coding system was developed which has enabled identification of injury, mechanism of injury, diagnostic and therapeutic procedures employed on all patients admitted to the Trauma Center. The numbering system developed is similar to but not identical to that used in the ICDA-8.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$ 337	-	-	\$337
FY77	178	-	-	178

PROGRESS

The principal investigator has departed and his successor is evaluating the protocol.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Investigation of the Etiology and Pathophysiology of Post-Traumatic Hepatic Dysfunction

WORK UNIT NO: 76/13

PRINCIPAL INVESTIGATOR: MAJ Hartong, MC

ASSOCIATE INVESTIGATORS: CPT R.S. Dixon, VC; MAJ J. Greene, MD

OBJECTIVES

To define the etiology and pathophysiology of post-traumatic hepatic dysfunction.

TECHNICAL APPROACH

Twenty-five laboratory bred beagles were utilized in the project and broken into various groups for study. A shock/trauma model was developed and utilized in this project. Liver function tests, blood gases, tissue pO2 and pH were measured in all animals. Sequential liver biopsies were performed.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$ 235	\$7325	\$23000	\$32,682
FY77	\$ 178	-	-	178

PROGRESS

The principal investigator has departed and his successor is evaluating the protocol.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: An Investigation of the Effect of Supplemental Oxygen on
Chemically Induced Fat Embolization

WORK UNIT NO: 76/24

PRINCIPAL INVESTIGATOR: CPT Foret, MD

ASSOCIATE INVESTIGATORS: CPT Hill, MD

OBJECTIVES

To determine whether or not supplemental oxygen prevents or lessens the potentially lethal effects of chemically induced fat embolization in dogs.

TECHNICAL APPROACH

Clinical observations as well as lung scans are generally accepted as criteria for determination of the presence of fat embolism syndrome. In this study laboratory parameters and lung scans are obtained for a 5-day period in beagles following injection of oleic acid. This data is collected from dogs supported on either room air or supplemental oxygen.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY76	\$2357	\$2200	-	\$4560
FY77	178	-	-	178

PROGRESS

Animal testing was suspended temporarily in order to evaluate preliminary work for possible improvements in technique, including discontinuance of oleic acid for embolization. A new primary investigator has assumed responsibility for the study.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Early Detection of Fatigue Fracture by Bone Scanning with
Tc-99 Bone Scan Agents

WORK UNIT NO: 76/31

PRINCIPAL INVESTIGATOR: CPT Snowdy, MD

ASSOCIATE INVESTIGATORS: Nuclear Medicine Staff

OBJECTIVES

To demonstrate if bone scans can detect fatigue fractures and/or stress reactions in bone in military personnel, etc.

TECHNICAL APPROACH

Patients with suspected stress fractures of bone are given bone scans on a "stat" or "ASAP" basis - usually the day after seen by Orthopedic physicians.

FUNDING:	<u>Civ Sal</u>	<u>Equip, Supp</u>	<u>OPA</u>	<u>Total</u>
FY76	\$337	-	-	\$ 337
FY77	-	-	-	-

PROGRESS

The efficacy of detection of stress fractures by bone imaging is now well established. The current work is directed toward establishing the earliest time at which the bone images become positive.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Proposal for Joint Study by Orthopedic Service, Dept of Clinics
and Radiology

WORK UNIT NO: 76/32

PRINCIPAL INVESTIGATOR: MAJ Ewart, MD

ASSOCIATE INVESTIGATORS: MAJ Shubert, MD

OBJECTIVES

To compare the clinical entity of low back pain with the presence of radiographic anomalies of the lumbo-sacral spine.

TECHNICAL APPROACH

Group analysis in a prospective fashion taking into account high risk categories. Personnel undergoing separation physicals (retirement, etc) will be assessed radiographically for the presence of lumbosacral anomalies. This evaluation will be correlated with previous history and consultations for low back pain.

<u>FUNDING:</u>	<u>Civ Sal</u>	<u>Equip,Supp</u>	<u>OPA</u>	<u>Total</u>
FY77	\$888	-	-	\$888

PROGRESS

Material was presented in a paper to the Society of Military Orthopedic Surgeons, Wash, D.C. Nov 1976. An updated report is similarly scheduled to be given at the same meeting in San Antonio in November 1977. It is of great interest that most anomalies occur in the same relative numbers in both the symptomatic and asymptomatic.

STATUS: Ongoing

CLINICAL INVESTIGATIONS SERVICE
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

DETAIL SHEET

TITLE: Pathophysiology and Treatment of Hemorrhagic and Traumatic Shock

WORK UNIT NO: 77/24

PRINCIPAL INVESTIGATOR: LTC Gary L. Neal, MD

ASSOCIATE INVESTIGATORS: Dr. Robert M Hardaway MII; CPT R S Dixon VC

OBJECTIVES

To study the pathophysiology and treatment of hemorrhagic and traumatic shock and the effect of vasodilation, steroids and fibrinolysin on these types of shock.

TECHNICAL APPROACH

Disseminated Intravascular Coagulation (DIC) and fatality have been shown to require the presence of slow capillary flow (shock) and the presence of a thromboplastic material in the blood stream. It is proposed to test the efficacy of phenoxvbenzamine (an alpha blocking agent), steroids, and fibrinolysin in the prevention of DIC following traumatic shock.

FUNDING:	Civ Sal	Equip, Supp	OPA	Total
FY77	\$12,187	\$ 8,997	\$1802	\$22,986

PROGRESS

New project.

STATUS: Ongoing

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